UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JIM KISER,

Plaintiff,

vs.

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant.

Civil Action No.: 1:07-cv-02959

ANSWER AND DEFENSES OF DEFENDANT NOVARTIS PHARMACEUTICALS CORPORATION TO PLAINTIFF'S COMPLAINT

JURY DEMAND

Defendant Novartis Pharmaceuticals Corporation ("NPC") responds to plaintiff's Complaint ("the Complaint") as follows:

1. The allegations in Paragraph 1 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint and therefore denies the same. NPC denies that any injuries alleged in the Complaint were caused by Aredia® and/or Zometa®.

2. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 2 of the Complaint and therefore denies the same.

3. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts are "at all times herein mentioned" and therefore NPC is unable to respond to the allegations in Paragraph 3 of the Complaint. To the extent that a response is required, NPC admits that it is a corporation incorporated under the laws of the state of Delaware with its

principal offices located in East Hanover, New Jersey. NPC denies the remaining allegations in Paragraph 3 of the Complaint.

4. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts are "at all times herein mentioned" and therefore NPC is unable to respond to the allegations in Paragraph 4 of the Complaint. To the extent that a response is required, NPC admits that it does business in the States of New York and Florida. NPC denies the remaining allegations in Paragraph 4 of the Complaint.

5. The allegations in Paragraph 5 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 5 of the Complaint and therefore denies the same.

6. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts in Paragraph 6 and is therefore unable to respond. To the extent that a response is required, NPC admits that it labels, tests, markets, distributes, and sells Zometa® and that it labels, sells, and distributes Aredia®. NPC admits that in the past it did test and market Aredia®. NPC denies the remaining allegations in Paragraph 6 of the Complaint.

7. In response to Paragraph 7 of the Complaint, NPC denies that Zometa® is a brand name under which NPC sells "zolodrenic" acid. NPC affirmatively avers that Zometa® is a brand name under which NPC sells zoledronic acid. NPC admits that Aredia® is a brand name of pamidronate disodium. NPC admits that Aredia® and Zometa® are bisphosphonic acids. NPC admits that Aredia® and Zometa® are given intravenously to cancer patients. NPC denies the remaining allegations in Paragraph 7 of the Complaint.

8. In response to Paragraph 8 of the Complaint, NPC states that Aredia® and Zometa® are approved by the Food and Drug Administration ("FDA") for the indications listed on each product's label. NPC denies the remaining allegations in Paragraph 8 of the Complaint to the extent that they mischaracterize or misstate information contained on the label for Aredia® or Zometa®.

9. NPC lacks sufficient knowledge or information to determine the meaning of the term "product literature" and what time periods plaintiff asserts in Paragraph 9 and is therefore unable to respond. To the extent that a response is required, NPC denies the allegations in Paragraph 9 of the Complaint.

10. NPC admits that it received information in 2002 that patients treated with Aredia® and/or Zometa® presented with osteonecrosis of jaw. NPC denies the remaining allegations in Paragraph 10 of the Complaint.

11. NPC admits that in 2004, Dr. Ruggiero and others published an article entitled "Osteonecrosis of the Jaws Associated with the Use of Bisphosphonates: A Review of 63 cases," in the Journal of Oral and Maxillofacial Surgery. NPC admits that the quoted language appears in this article, but avers that the article speaks for itself. NPC denies the remaining allegations in Paragraph 11 of the Complaint to the extent that they mischaracterize or misstate information contained in said article.

12. The allegations in Paragraph 12 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC admits that it sent correspondence to medical professionals on September 21, 2004 and to dentists on May 5, 2005

addressing the subject of osteonecrosis of the jaw. NPC denies the remaining allegations in Paragraph 12 of the Complaint.

13. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 13 of the Complaint and therefore denies the same.

14. NPC lacks sufficient knowledge or information to determine whether plaintiff was given and/or injected with Zometa® or Aredia® and if he developed osteonecrosis of the jaw and therefore denies those allegations. The remaining allegations in Paragraph 14 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 14 of the Complaint.

15. NPC lacks sufficient knowledge or information to determine whether plaintiff was given and/or injected with Aredia® and Zometa® and whether plaintiff suffered any injury and therefore denies the same. The remaining allegations in Paragraph 15 of the Complaint and its subparts (a) through (g) constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 15 and its subparts (a) through (g).

16. In response to Paragraph 16 of the Complaint, NPC incorporates by reference its responses to the allegations in Paragraphs 1 through 15 of the Complaint.

17. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts in Paragraph 17 and is therefore unable to respond. To the extent that a response is required, NPC admits that it labels, tests, markets, distributes, and sells Zometa® and that it

labels, sells, and distributes Aredia®. NPC admits that in the past it did test and market Aredia®. NPC denies the remaining allegations in Paragraph 17 of the Complaint.

18. The allegations in Paragraph 18 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 18 of the Complaint. NPC specifically denies that Aredia® and/or Zometa® are "defective" or "unreasonably dangerous."

19. The allegations in Paragraph 19 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 19 of the Complaint. NPC specifically denies that Aredia® and/or Zometa® were "defective."

20. The allegations in Paragraph 20 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 20 of the Complaint. NPC specifically denies that Aredia® and/or Zometa® were "defective."

21. The allegations in Paragraph 21 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 21 of the Complaint. NPC specifically denies that Aredia® and/or Zometa® were "defective."

22. NPC lacks sufficient knowledge or information to determine whether plaintiff suffered any injury and therefore denies that allegation. The remaining allegations in Paragraph 22 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 22 of the Complaint.

23. In response to Paragraph 23 of the Complaint, NPC incorporates by reference its responses to the allegations in Paragraphs 1 through 15 of the Complaint.

24. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts in Paragraph 24 and is therefore unable to respond. To the extent that a response is required, NPC admits that it labels, tests, markets, distributes, and sells Zometa® and that it labels, sells, and distributes Aredia®. NPC admits that in the past it did test and market Aredia®. NPC denies the remaining allegations in Paragraph 24 of the Complaint.

25. The allegations in Paragraph 25 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 25 of the Complaint.

26. The allegations in Paragraph 26 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 26 of the Complaint.

27. NPC lacks sufficient knowledge or information to determine whether plaintiff suffered any injury and therefore denies that allegation in Paragraph 27 of the Complaint. The remaining allegations in Paragraph 27 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 27 of the Complaint.

28. In response to Paragraph 28 of the Complaint, NPC incorporates by reference its responses to the allegations in Paragraphs 1 through 15 of the Complaint.

29. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts in Paragraph 29 and is therefore unable to respond. To the extent that a response is required, NPC admits that it labels, tests, markets, distributes, and sells Zometa® and that it

labels, sells, and distributes Aredia®. NPC admits that in the past it did test and market Aredia®. NPC denies the remaining allegations in Paragraph 29 of the Complaint.

30. The allegations in Paragraph 30 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC admits that applicable law imposes certain duties upon manufacturers and distributors of products, but denies that Paragraph 30 accurately sets forth those duties. NPC denies the remaining allegations in Paragraph 30 of the Complaint.

31. The allegations in Paragraph 31 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 31 of the Complaint.

32. The allegations in Paragraph 32 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 32 of the Complaint.

33. NPC lacks sufficient knowledge or information to determine whether plaintiff suffered any injury and therefore denies that allegation in Paragraph 33 of the Complaint. The remaining allegations in Paragraph 33 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 33.

34. In response to Paragraph 34 of the Complaint, NPC incorporates by reference its responses to the allegations in Paragraphs 1 through 15 of the Complaint.

35. The allegations in Paragraph 35 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 35 of the Complaint.

36. The allegations in Paragraph 36 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 36 of the Complaint and therefore denies the same.

37. The allegations in Paragraph 37 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 37 of the Complaint. NPC specifically denies any causal connection exists between Zometa® treatment and osteonecrosis of the jaw or Aredia® treatment and osteonecrosis of the jaw.

38. NPC lacks sufficient knowledge or information to determine whether plaintiff suffered any injury and therefore denies that allegation in Paragraph 38 of the Complaint. The remaining allegations in Paragraph 38 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 38.

39. In response to Paragraph 39 of the Complaint, NPC incorporates by reference its responses to the allegations in Paragraphs 1 through 15 of the Complaint.

40. The allegations in Paragraph 40 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 40 of the Complaint.

41. The allegations in Paragraph 41 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 41 of the Complaint and therefore denies the same.

42. The allegations in Paragraph 42 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 42 of the Complaint.

43. NPC lacks sufficient knowledge or information to determine whether plaintiff suffered any injury and therefore denies that allegation in Paragraph 43 of the Complaint. The remaining allegations in Paragraph 43 constitute legal conclusions to which no response is required. To the extent that a response is required NPC denies the allegations in Paragraph 43 of the Complaint.

44. With respect to the allegations in the unnumbered paragraph and its subparts (a) through (c) following Paragraph 43, which begins with the word "WHEREFORE," these allegations constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies that plaintiff is entitled to any of the relief requested therein.

45. Every allegation in the Complaint that is not specifically and expressly admitted in this Answer is hereby specifically and expressly denied.

AFFIRMATIVE DEFENSES

1. The Complaint, in whole or part, fails to state a claim or cause of action against NPC upon which relief can be granted.

2. Venue is inconvenient to the parties in the United States District Court for the Southern District of New York, and this matter should be transferred to an appropriate jurisdiction.

3. The doctrines contained in Restatement (Second) of Torts § 402A, Comment K, bar plaintiff's claims against NPC in whole or in part.

4. The doctrine(s) contained in Restatement (Third) of Torts, Product Liability §§ 4 and 6, bar plaintiff's claims against NPC in whole or in part.

5. Applicable statutes of limitations or repose bar plaintiff's claims in whole or in part.

6. Plaintiff's misuse or abnormal use of the products or failure to follow instructions bar the plaintiff's claims in whole or in part.

7. The alleged injuries to plaintiff were proximately caused by the misuse, abuse, alteration, and/or failure to properly utilize, maintain, or care for the product by persons other than NPC.

8. If plaintiff used a product sold by NPC, then plaintiff's claims are barred, in whole or in part, because plaintiff assumed the risks disclosed by the product labeling, by the prescribing physicians, or by other persons or entities.

9. Any alleged negligent or culpable conduct of NPC, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of plaintiff's alleged injuries.

10. If plaintiff used a product sold by NPC, plaintiff used the product for "off-label" purposes, which bars the plaintiff's claims.

11. The "learned intermediary" doctrine bars plaintiff's claims.

12. Plaintiff's claims are barred, in whole or in part, because the products at issue were designed, manufactured, marketed and labeled with proper warnings, information, cautions and instructions, in accordance with the state of the art and the state of scientific and technological knowledge. *See, e.g.*, Fla. Stat. § 768.1257.

13. Plaintiff's claims are barred, in whole or in part, because the labels and information accompanying the products at issue were approved by the U.S. Food and Drug Administration or other appropriate regulatory agencies.

14. Plaintiff's claims are barred, in whole or in part, because the pharmaceutical products at issue were approved by the FDA.

15. Plaintiff's claims are barred, in whole or in part, because the products at issue were not defective or unreasonably dangerous in that they complied with, at all relevant times, all applicable government safety standards.

16. Plaintiff's claims are preempted, in whole or in part, by applicable federal law relating to the design, testing, producing, manufacturing, labeling, distributing, modeling, processing, and supply of Aredia® and/or Zometa®.

17. Plaintiff's claims are barred, in whole or in part, because plaintiff's injuries, if any, were the result of conduct of plaintiff, independent third parties, and/or events that were

extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent, intervening and superseding causes of the alleged injuries, including but not limited to plaintiff's pre-existing medical conditions.

18. If plaintiff suffered injury or damages as alleged, which is denied, such injury or damage resulted from acts or omissions of persons or entities for which NPC is neither liable nor responsible or resulted from diseases and/or causes that are not related or connected with any product sold, distributed, or manufactured by NPC. Such acts or omissions on the part of others or diseases or causes constitute an independent, intervening and sole proximate cause of plaintiff's alleged injury or damages.

19. Plaintiff's claims are barred, in whole or in part, because plaintiff's alleged injuries, if caused by Aredia® and/or Zometa®, which is denied, were the result of plaintiff's own idiosyncratic reactions.

20. Plaintiff failed to mitigate, which limits plaintiff's damages, if any, in whole or in part.

21. Aredia® and Zometa® were fit and proper for their intended purposes and the social utility of the drugs outweighed any possible risk inherent in the use of the products.

22. NPC has no legal relationship or privity with plaintiff and owes no duty to plaintiff by which liability could be attributed to it.

23. The claims of plaintiff should be diminished in whole or in part in the amount paid to plaintiff by any party or non-party with whom plaintiff has settled or may settle.

24. Plaintiff's claims are barred, reduced and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

25. NPC made no warranties of any kind, express or implied, or any representations of any nature whatsoever to plaintiff. If any such warranties were made, whether express or implied, which NPC specifically denies, then plaintiff did not rely on any such representations or warranties and/or failed to give notice of any breach thereof.

26. Notwithstanding the claims and contentions of plaintiff, plaintiff received all or substantially all of the benefit from the products that he hoped and intended to receive, and, to that extent, any damages and/or restitution that plaintiff might be entitled to recover from NPC must be correspondingly reduced.

27. Plaintiff's causes of action are barred in whole or in part by plaintiff's own contributory/comparative negligence.

28. Plaintiff's recovery, if any, shall be reduced by those payments that plaintiff receives from collateral sources.

29. If plaintiff has been injured or damaged, no injury or damages being admitted, such injuries were not caused by an NPC product.

30. Plaintiff's claims are barred, in whole or in part, because the products at issue were not defective or unreasonably dangerous in that they complied with, at all relevant times, all applicable government safety standards and their benefits exceeded any associated risks. NPC complied with applicable regulations of the Federal Food & Drug Administration, and to the extent that Florida law applies is entitled to application of F.S. §768.1256.

31. Plaintiff is not entitled to collect duplicative damages, should any be awarded, or damages for any cause of action not specifically pleaded in this Complaint, and claims for such damages are therefore barred.

32. Plaintiff is responsible, in whole or in part, for any injuries plaintiff suffered as a result of plaintiff's own negligence and plaintiff's acts or omissions bar plaintiff's recovery to the extent that plaintiff's individual relative degree of fault is equal to or greater than the fault of NPC, no fault being admitted. In the alternative, if plaintiff's individual relative degree of fault is less than that of NPC, no fault being admitted, then plaintiff's right to recover is diminished in an amount based upon plaintiff's individual relative degree of fault.

33. If any loss, damages, injury, harm, expense, diminution or deprivation alleged by plaintiff was caused by Aredia® and/or Zometa®, which NPC denies, NPC is entitled to a reduction in any damages awarded which are attributable to plaintiff's incurred risk in continuing to use a product which, under the specific circumstances of said use, an ordinary person would have known was potentially causing health problems.

34. To the extent that the incident referred to in the Complaint was caused, in whole or in part, by persons or entities not under NPC's control, NPC is entitled to have its liability, if any, reduced pursuant to the provisions of Florida Statute § 768.81. The persons or entities referred to in this paragraph are presently unknown to the defendant and will be identified in a timely manner consistent with Nash v. Wells Fargo, 678 So.2d 1262 (Fla. 1996).

35. NPC hereby gives notice that it intends to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserves its right to amend this Answer to assert such defenses.

WHEREFORE, Defendant NPC demands judgment in its favor and against plaintiff, dismissing plaintiff's Complaint with prejudice, together with the costs of suit and such other relief as the Court deems equitable and just.

JURY DEMAND

Defendant Novartis Pharmaceuticals Corporation demands a jury trial as to all issues so triable.

Dated: May 8, 2007

Respectfully submitted,

s/ Ethan D. Stein
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CERTIFICATE OF SERVICE

I hereby certify that on May 8, 2007, the Answer and Defenses of Defendant Novartis Pharmaceuticals Corporation to Plaintiff's Complaint was filed with the Clerk of the Court and served in accordance with the Southern District's Rules on Electronic Service upon the following parties and participants:

Daniel A. Osborn, Esq.
Russel H. Beatie, Esq.
Beatie and Osborn LLP
521 Fifth Avenue, 34th Floor
New York, NY 10175

I further certify that on May 8, 2007, I served a true and correct copy of the Answer and Defenses of Defendant Novartis Pharmaceuticals Corporation to Plaintiff's Complaint, by United States Mail, postage prepaid, on:

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Beverly Hills, CA 90212

The Offices of Jeffrey C. Bogert
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s/ Ethan D. Stein
Ethan D. Stein